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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,236	03/11/98	LUO	Y EX98-001

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HM12/0831

EXAMINER

LEE, L

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED:

08/31/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/041,236

Applicant(s)

Luo

Examiner

Li Lee

Group Art Unit

1645



☒ Responsive to communication(s) filed on Jun 18, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10-22 is/are pending in the application.

Of the above, claim(s) 14-22 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's amendment filed on June 18, 1999 (Paper Number 7) has been received and entered. Claims 1-9 have been canceled and claims 10-22 have been added, consequently claims 10-22 are pending in the instant application. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the new claims 14-18 which are drawn to non-elected Group II of nucleic acid and expression system and new claims 19-22 which are drawn to non-elected Group III of a method for modulation a cellular physiology by using a polypeptide are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142 (b) and MPEP § 821.03. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

For reasons as set forth in the previous Office action the restriction requirement is deemed to be proper and is therefore made FINAL.

Oath/Declaration

2. The objection of Oath/Declaration, as being defective because lacking inventors original signatures is withdrawn in view of inventors signature are present on the oath.

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The following new grounds of rejection are applied to the newly added claims.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1 and 2 under 35 U.S.C. 112, first paragraph, because the specification, as being enabling for a polypeptide selected from the group consisting of (a), (b), © and (d) of SEQ ID NO:2, does not reasonably provide enablement for multi/shuffled domains polypeptide of SEQ ID NO:2, is maintained as applied to newly added claims 10-13.

Applicant's are asserting that the claims do not recite "multi/shuffled" and the claims intend to indicate recombinantly expressed polypeptides which may be covalently coupled to other sequences rather than SEQ ID NO:2 or recited fragments. Applicant's arguments have been fully considered but are not found to be persuasive.

Applicant's arguments are not found to be persuasive in view of the broadest interpretation of the claims which read on a polypeptide having more than one of the recited residues of SEQ ID NO:2 in any number of repeats of peptides (a), (b), or/and © indicating multi domains (e.g., a peptide having multi domains of aa-b-c) and in any order of (a), (b), or/and © indicating shuffled domains (e.g., a peptide having shuffled domains of c-aa-b). However, the scope of applicant's claims to "an isolated polypeptide comprising at least one of (a) ..., (b) ..., and © ...of SEQ ID NO:2" is not enabled by the original disclosure. The specification only teaches the use of a single domain of polypeptide SEQ ID NO:2. The specification does not provide any guidance of how to use any multi/shuffled domain SEQ ID NO:2 polypeptide which act as an sema K1 as instantly claimed nor does the specification disclose specific characteristics

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for such multi/shuffled domain SEQ ID NO:2 polypeptide. A polypeptide having multi domains or domain shuffling can dramatically alter the folding of a protein. The biological function of such multi domains or domain shuffling proteins are unpredictable due to unpredictable biological activity of proteins misfolding. The specification has not conceived how to use any other functionally equivalent multi domains or domain shuffling proteins of SEQ ID NO:2 polypeptide. Since, the specification lacks any guidance of any multi/shuffled domains of SEQ ID NO:2 polypeptide, it is not enabled for this language because it fails to enable the skilled artisan to envision how to use the multi/shuffled domain of SEQ ID NO:2 polypeptide, as well as the detailed chemical structure of the claimed multi/shuffled domain of SEQ ID NO:2 polypeptide, as well as the screening method of obtaining them, one of skilled in the art would be unable to use the multi/shuffled domain of SEQ ID NO:2 polypeptide encompassed by the instant claims.

In view of the lack of any guidance or teaching with respect to using the multi/shuffled domains of SEQ ID NO:2 polypeptide that functions equivalently to the protein of SEQ ID NO:2, or with respect to any potential means of using multi/shuffled domains of SEQ ID NO:2 polypeptide, the unpredictability associated with using multi/shuffled domains of SEQ ID NO:2 polypeptide encompassed in the scope of the claim as set forth above, the lack of teaching even a beginning point for multi/shuffled domain of SEQ ID NO:2 polypeptide for routine experimentation, the lack of a method to use multi/shuffled domain of SEQ ID NO:2 polypeptide, and the lack of working examples commensurate in scope with the instant claims, the skilled

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artisan would be forced into undue experimentation to practice (i.e. use or make) the invention as is broadly claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite for recitation of "residues 1-10; ...and residues 598-606 of SEQ ID NO:2". It is not clear whether the applicants intend to indicate that these recited residues in claim 11 are contained in the 100 contiguous residues of SEQ ID NO:2, 60 contiguous residues of SEQ ID NO:2, or 12 contiguous residues of SEQ ID NO:2 or that these recited residues in claim 11 are contained in any part of SEQ ID NO:2.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee, M.D., Ph.D. whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee, M.D., Ph.D.
August 28, 1999


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600